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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
NOBUKAZU TANAKA, ET AL.	: EXAMINER: MILLIGAN, ADAM C.
SERIAL NO: 10/576,257	:
FILED: APRIL 27, 2007	: GROUP ART UNIT: 1612
FOR: TABLET QUICKLY DISINTEGRATING IN ORAL CAVITY	:

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Now comes Mr. Nobukazu TANAKA who states that:

1. I am a named inventor of the above-identified application.

2. I have been employed by Fuji Chemical Industry Co., Ltd., for 24 years as a scientific researcher in the field of pharmaceuticals.

3. I understand the English language, or at least the contents of the Declaration were made clear to me prior to executing the same.

4. The comparative experimental data presented in the following Table A demonstrates that superior properties with respect to an excellent balance of both improved oral disintegration times and tabletting properties are exhibited by a composition having a weight ratio of mannitol to other saccharide(s) of (98-75) : (2-25) in accordance with the present invention, as compared to the inferior properties exhibited by a conventional composition having a weight ratio of mannitol to other saccharide(s) outside (98-75) : (2-25).

5. Experimental Results:

Table A

Tablet Composition	Comparative Example A	Example B	Example 9	Example C	Comparative Example D
Weight Ratio of mannitol : lactose	100 : 0	98 : 2	90 : 10	75 : 25	65 : 35
Mannitol	280	274.4	252	210	182
Lactose	0	5.6	28	70	98
Crystalline cellulose	60	60	60	60	60
Crospovidone	32	32	32	32	32
Mg aluminometasillicate	28	28	28	28	28
Tabletting Pressure (kgf)	340	380	310	260	240
Oral Disintegration Time (sec)	16	26	17	34	73
Tabletting troubles	**Yes***	No	No	No	No

* The tablet composition stuck to the punches, and the shape of the obtained tablets was not satisfactory.

6. The tablet compositions of Examples B and C, and Comparative Examples A and D, were prepared according Example 9 in the present specification, with the exception of alternatively containing mannitol and the other saccharide(s) in the weight ratio specified in Table A above.

7. This evidence clearly demonstrates that the tablet compositions of Examples B, 9 and C, which contain mannitol and other saccharide(s) in the weight ratio of (98-75) : (2-25) in accordance with the present invention, exhibit superior properties with respect to an excellent balance of both improved oral disintegration times and tabletting properties, as compared to the inferior tabletting property exhibited by the tablet composition of Comparative Example A, which has a weight ratio of mannitol and other saccharide(s) of (100) : (0), and the inferior oral disintegration time property exhibited by the tablet composition of Comparative Example D, which has a weight ratio of mannitol and other saccharide(s) of (65) : (3), which is similar to the weight ratio described in Koike.

8. In my opinion, Examples similar in composition to Examples B, 9 and C above, but containing, in place of lactose, other saccharide(s) selected from sorbitol, erythritol, maltitol, sucrose, glucose, fructose, maltose, trehalose, paratinit and paratinose, would exhibit comparable properties to those of Examples B, 9 and C above with respect to an excellent balance of both improved oral disintegration times and tabletting properties (See e.g., the Table at page 30 of the present specification). I am aware of no reason to believe otherwise.

9. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Nobukazu Tanaka
Signature of Mr. Nobukazu TANAKA

May 11, 2010
Date